

order establishes that for a sunscreen drug product containing bemotrizinol as a sunscreen active ingredient to be legally marketed without an approved application under section 505 of the FD&C Act (21 U.S.C. 355), among other requirements, it must conform to certain conditions that address the concentration of bemotrizinol in the sunscreen drug product, permitted combinations of bemotrizinol with other sunscreen active ingredients and with skin protectant active ingredients, and permitted dosage forms. Specific to dosage forms, the final order permits sunscreen drug products containing bemotrizinol to be in the following dosage forms: oil, lotion, cream, gel, butter, paste, ointment, stick, and spray, provided that the sunscreen drug product in spray dosage form is manufactured and packaged with no propellant or is manufactured and packaged in a spray delivery system where all propellant is isolated from the drug product formulation within the container closure system, and there is no contact between the propellant and the drug product formulation.

Final order OTC000039 also includes minor stylistic and formatting changes to improve the readability, clarity, and presentation of OTC Monograph M020.

A notice of availability of the proposed order titled “Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use” was announced in the **Federal Register** on December 12, 2025 (90 FR 57765). FDA considered timely submitted comments on the proposal to amend OTC Monograph M020 to add bemotrizinol as a sunscreen active ingredient. After considering comments, FDA did not make changes to the final order.

II. Paperwork Reduction Act of 1995

Final order OTC000039 is issued under section 505G(b)(1) of the FD&C Act. Under section 505G(o) of the FD&C Act, the Paperwork Reduction Act of 1995 (Chapter 35 of title 44, United States Code) does not apply to collections of information made under section 505G of the FD&C Act. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required for collections of information, if any, in a final order issued under section 505G.

III. Electronic Access

The final order can be accessed on the OTC *Monographs@FDA* portal at <https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm>. Under the “Administrative Orders” banner, click

on the desired link under the “Order ID” heading and follow the prompts. FDA established this information technology system with a web portal that can be accessed through FDA’s website. The OTC *Monographs@FDA* portal provides a resource for the public to view administrative orders (proposed, final, and interim final orders), as well as related supporting documents, for OTC Monograph Drugs and view OTC Monographs. In the future, the OTC *Monographs@FDA* portal will facilitate the public’s ability to submit, search, and view comments and data for proposed and interim final orders.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

HHS Request for Comment on Chronic Disease of Addiction

AGENCY: US Department of Health and Human Services (HHS or the Department).

ACTION: Notice of Request for Information (RFI) regarding substance research, policy, and strategies to improve the prevention, treatment, recovery of chronic disease of addiction and mental illness and how to promote the Great American Recovery Initiative.

SUMMARY: Thanks to President Trump’s leadership, since 2017, the country has made significant progress in addressing mental health and substance use. However, President Trump and HHS Secretary Kennedy realize that the Department and country have more work to do. To facilitate this effort, HHS invites public comment in response to this RFI on the research, development, programs, and policies that have been most successful in improving availability of and access to effective prevention, treatment, and recovery interventions for addiction, mental illness, and co-occurring substance use and mental disorders. The purpose of this RFI is to identify research, programs, and policies that have been successful and recommend novel policy ideas and gaps in research that could be addressed and implemented to further the Great American Recovery using existing funding.

DATES: Comments on this notice must be received by July 5, 2026.

ADDRESSES: Interested parties may submit comments electronically to

REPORTSCLEARANCEOFFICER@ahrq.hhs.gov with the subject line ‘Great American Recovery.’

FOR FURTHER INFORMATION CONTACT: Erica Moshtahedian, Agency for Healthcare Research and Quality (AHRQ) Chief of Staff, Department of Health and Human Services (HHS), Erica.Moshtahedian@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION: HHS is dedicated to promoting the health and well-being of the American people. To advance this goal, HHS is implementing President Trump’s Executive Order (E.O.) 14379 of January 29, 2026: *Addressing Addiction Through the Great American Recovery Initiative* and E.O. 14321 of July 24, 2025: *Ending Crime and Disorder on America’s Streets* that will bring back safety and trust to America’s communities.

This initiative represents a critical new step to strengthen federal guidance and grants to support the nation’s recovery, with a focus on prevention, treatment, and long-term resilience. It consists of:

Guidance

1. Strengthening Agency Collaboration

The Centers for Medicare & Medicaid Services (CMS), the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Administration for Children and Families (ACF) issued joint guidance to improve coordination between state Medicaid, substance abuse, mental health, and child welfare agencies, with a focus on youth mental health, substance use prevention, and early intervention.¹ SAMHSA and CMS also recently issued guidance concerning best practices for implementing behavioral health crisis services through Medicaid and CHIP.²

2. Engaging Faith-Based Providers

States receiving SAMHSA and ACF block grants and large formula grants were issued new guidance and best practices on how to include faith-based organizations as part of their provider networks. This includes SAMHSA’s State Opioid Response (SOR) grants and the Mental Health and Substance Use Block Grants.³

3. Development of Non-Opioid Options

The Food and Drug Administration (FDA) issued guidance in September 2025 to help expand non-opioid options

¹ <https://www.samhsa.gov/sites/default/files/dear-colleague-letter-moud.pdf>.

² <https://www.medicaid.gov/federal-policy-guidance/downloads/sho25004.pdf>.

³ <https://www.samhsa.gov/sites/default/files/dear-colleague-letter-faith-based-organizations.pdf>.

for chronic pain and to curb misuse.⁴ It addresses development of non-opioid analgesics with specific attention to establishing indications, trial design, appropriate patient populations, and meaningful outcomes.

4. Integration of Health Records

HHS aligned certain 42 CFR part 2 requirements with existing regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH) to enhance integration of behavioral health information with other medical records to improve patient health outcomes. The final rule provides the public with the ability to file complaints alleging violations of the Part 2 confidentiality provisions, requires Part 2 programs to provide notification of breaches of Part 2 records, and implements in regulation HHS's civil enforcement authority, including the potential for civil money penalties for violations.⁵ SAMHSA is reissuing funding for a Center of Excellence in Privacy of Health Information that will support integration and use of data compliance with patient privacy protections.

5. Implementing Medications for Opioid Use Disorder

ACF, in collaboration with SAMHSA developed a new option allowing states to leverage federal Title IV–E prevention funding as the payer of last resort to support access to FDA-approved medications for opioid use disorder.⁶ This action will help address the nation's opioid crisis, support long-term recovery, prevent foster care placements, and support and strengthen families when children are at imminent risk of entering foster care.

6. Ending Support for Harm Reduction

SAMSHA issued guidance to the field⁷ and terms and conditions⁸ across its grant portfolio to end support for counterproductive harm reduction efforts that facilitate illegal drug use and its deadly consequences. This guidance makes clear that safe use efforts and the provision of materials and drug

paraphernalia, like syringes for illegal drug use, are not allowed with SAMHSA funding, while supporting life-saving interventions including medications for opioid use disorder and opioid overdose reversal medications.

Resources

1. Recovery Housing

In September, SAMHSA awarded more than \$45 million in new supplemental funding to SOR recipients, with a focus on sober housing and recovery support for young adults.⁹

2. Health Technology

As part of a \$20 million Behavioral Health IT (BHIT) initiative, the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology and SAMHSA are awarding \$5 million to test a standardized set of behavioral health data elements to ensure interoperability and exchange of information across providers, states, and federal programs and help further the use of health technology to advance chronic disease of addiction and mental health care treatment, care coordination, and integration of behavioral and physical health care.¹⁰

4. STREETS Initiative

HHS announced the \$100 million Safety Through Recovery, Engagement, and Evidence-based Treatment and Supports—or STREETS—Initiative which will fund 8 localities to transform their homelessness services systems to focus on accountability, independence, and move away from damaging practices like harm reduction and housing first and to connect homeless people to the care for addiction, serious mental illness (SMI), and cooccurring mental and chronic disease of addiction.¹¹

5. Rural Communities Opioid Response

The Health Resources and Services Administration's (HRSA) Rural Communities Opioid Response Program¹² made a significant investment of \$145 million to support more than 200 active grant recipients. These recipients cover 2,000 rural

counties in 47 states and 2 territories, and serves approximately 2 million rural residents annually, highlighting the widespread impact of this program. This total budget includes 162 new awards made under competitive Notice of Funding Opportunities in FY 2026, while the remaining approximately 50 awards were noncompeting continuation awards. This initiative focuses on expanding access to comprehensive prevention, treatment, and recovery services for opioid and related chronic disease of addiction in rural communities across the nation. These efforts are coordinated with significant behavioral health investments being made in rural communities under the Rural Health Transformation Program established under Public Law 119–21, which CMS refers to as the Working Families Tax Cut (WFTC) legislation.¹³

6. SAMHSA Is Directing Targeted CCBHC Investments to Hard-Hit Communities

This effort includes recent funding awarded to a CCBHC in Philadelphia that serves the Kensington neighborhood.¹⁴ For decades, this neighborhood has been an epicenter of homelessness and addiction, but the introduction of illicit fentanyl and other emerging toxic illicit drugs such as xylazine and medetomidine have had a dramatic negative impact in an already struggling community. In FY 2026, more than additional CCBHC expansion grants will be awarded to communities across the United States with a focus on those most affected by overdose, addiction, and instability and building out recovery supports for addition or serious mental illness. SAMHSA will focus these grants on the 100 counties hardest hit by overdose deaths through point preferences in the grant competition.

7. SAMHSA Will Release an Assisted Outpatient Treatment (AOT) Funding Opportunity

This funding is to better support individuals with SMI, including homeless individuals. This opportunity will provide \$10 million in new funding to expand civil-commitment pathways, community-based treatment, and step-down services that prevent repeated hospitalization, incarceration, and housing instability. This is an important

⁴ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/development-non-opioid-analgesics-chronic-pain>.

⁵ <https://www.hhs.gov/hipaa/for-professionals/regulatory-initiatives/fact-sheet-42-cfr-part-2-final-rule/index.html>.

⁶ <https://www.samhsa.gov/sites/default/files/dear-colleague-letter-moud.pdf>.

⁷ <https://www.samhsa.gov/sites/default/files/dear-colleague-letter-executive-order-ending-crime-disorder-americas-streets-07302025.pdf>.

⁸ <https://www.samhsa.gov/sites/default/files/fy25-award-standard-terms-conditions.pdf>.

⁹ <https://www.hhs.gov/press-room/samhsa-awards-45-million-funding-support-sober-housing-services.html>.

¹⁰ <https://healthit.gov/news/astp-nc-announces-selection-of-nationwide-pilot-programs-to-improve-behavioral-health-data-exchange/>.

¹¹ <https://www.hhs.gov/press-room/secretary-kennedy-announces-100-million-investment-great-american-recovery.htm>.

¹² <https://www.hrsa.gov/rural-health/opioid-response>.

¹³ <https://www.cms.gov/files/document/rht-program-state-provided-abstracts.pdf>.

¹⁴ <https://www.samhsa.gov/about/news-announcements/statements/2025/statement-from-samhsa-pdas-dr-art-kleinschmidt-2m-award-pilot-program-help-homeless-people-mental-illness-suds-treatment>.

aspect in compliance with Executive Order 14321, Ending Crime and Disorder on America's Streets. SAMHSA is also providing technical assistance to Assisted Outpatient Treatment (AOT) grant recipients and the field to support the development of and implementation of AOT through the GAINS Center for Behavioral Health and Justice Transformation.

8. SAMHSA Is Working To Eliminate Hepatitis C To Improve Care for Individuals With Mental Illness & Addiction

SAMHSA awarded a total of \$98 million for the Hepatitis C Elimination Initiative Pilot (otherwise known as Hep C Free).¹⁵ SAMHSA anticipates the program will serve an estimated 16,000 Americans in FY 2026. These resources will help prevent, treat, and cure Hepatitis C in individuals with chronic disease of addiction and/or SMI and reduce the spread of this deadly disease. This initiative dovetails with the Make America Healthy Again goal of ending chronic diseases.

Request For Information

For this RFI, more information is desired from the public, patients, people with lived experience of addiction and recovery, healthcare providers, community-based organizations, faith-based organizations, policymakers and others on improvements to the programs and policies of the United States Government and HHS that focus on substance use, including opioid and polysubstance use, prevention, treatment, and recovery as well as mental health treatment prevention, and recovery in all age groups. The questions below are of particular interest.

We encourage commenters to include supporting facts, research, and evidence in their comments. When doing so, commenters are encouraged to cite all sources and data sets with links as part of the comment. Providing such citations and documentation will assist us in analyzing the comments.

This RFI should not be construed as a policy, solicitation for applications, or as an obligation on the part of the government to provide support for any ideas in response to it. HHS will use the information submitted in response to this RFI at its discretion and will not provide comments on any respondent's submission. However, responses to this RFI may be reflected in future solicitation(s) or policies. The

information provided will be analyzed and may appear in reports. Please do not submit any protected health information or confidential material that you do not wish to be made available to the public.

An example of comments we are looking for: In the first Trump Administration, HHS helped coordinate take back days which took millions of pills out of homes and helped make the opioid overdose reversal medication naloxone more widely available. While these were significant policy wins, HHS can better coordinate with other agencies to achieve the President's goals by ensuring there is alignment in goals to address addiction.

Questions

1. What are programs or interventions that have rigorous, empirical evidence of effectiveness in improving outcomes for:

- substance use prevention, treatment, and recovery?
- mental illness prevention, treatment, and recovery?
- care for co-occurring mental and chronic disease of addiction?

If applicable, provide 2–3 programs or policies for question (1). List each activity separately and include one of the following for each.

- i. Title
- ii. Type of activity
- iii. Date
- iv. Link (if applicable)
- v. Description (3–5 sentences)
- vi. Statutory authority

2. Using existing funding, what policies or changes to federal programs might improve outcomes in:

- substance use prevention, treatment, and recovery?
- mental illness, prevention, treatment, and recovery?
- care for co-occurring mental and chronic disease of addiction?

Provide 2–3 policy ideas for question (2). List each activity separately and include one of the following for each.

- i. Title
- ii. Type of activity
- iii. Description (3–5 sentences)
- iv. Statutory authority

3. E.O. 14379 calls for Federal efforts to, “increase awareness of the disease of addiction” and to “foster a culture that celebrates recovery.” How can Federal policies and programs be improved to mitigate the stigma against Americans seeking addiction treatment and recovery? Provide 2–3 policy ideas for question (3). List each activity separately and include one of the following for each.

- i. Title
- ii. Type of activity
- iii. Description (3–5 sentences)
- iv. Statutory authority

4. E.O. 14379 calls for Federal efforts to, “help Americans receive the treatment they need” including “aligning relevant Federal programs” and “all necessary steps to coordinate the Federal Government’s response to the addiction crisis.” One problem in this area is insufficient supply of addiction and mental health counselors (a shortfall estimated by HHS–HRSA at about 77,050 and 99,780 respectively).¹⁶ This means it is harder for Americans to find the help they need in their area and covered by their insurance, especially in rural or underserved areas. How can Federal policies and programs be improved to address this practitioner supply issue to better ensure that every American seeking addiction treatment can find affordable help covered by their insurance in their area? Provide 2–3 policy ideas for question (4). List each activity separately and include one of the following for each.

- i. Title
- ii. Type of activity
- iii. Description (3–5 sentences)
- iv. Statutory authority

5. How can HHS strengthen its ability to evaluate the effectiveness of substance use and mental health prevention, treatment, and recovery programs and initiatives? How can the Department leverage data modernization, advanced analytics, and emerging technologies such as artificial intelligence to enable performance measurement on a real time or continuing basis? Provide 2–3 policy or operational ideas for question (5). List each activity separately and include one of the following for each.

- i. Title
- ii. Type of activity
- iii. Description (3–5 sentences)
- iv. Statutory authority

Robert F. Kennedy, Jr.,

Secretary, United States Department of Health and Human Services.

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¹⁵ <https://www.samhsa.gov/newsroom/press-announcements/20250924/samhsa-awards-98m-for-hepatitis-c-elimination-initiative-pilot>.

¹⁶ <https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/Behavioral-Health-Workforce-Brief-2025.pdf>.